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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, Defendants.	Case No. 3:23-cv-14221-ZNQ-DEA **DEFENDANTS' COMBINED MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

For more than 30 years, Congress has imposed limits on how much federal agencies pay for prescription drugs. Manufacturers that wish to sell their drugs to the Department of Defense and the Department of Veterans Affairs do so at statutorily defined ceiling prices, and both agencies have authority to negotiate prices further below those ceilings. *See* 38 U.S.C. § 8126(a)–(h). Building on this model in the Inflation Reduction Act (IRA) of 2022, Pub. L. No. 117-169, Congress granted the Secretary of Health and Human Services similar authority to negotiate how much Medicare will pay for pharmaceutical products that lack generic (or biosimilar) competition and account for a disproportionate share of Medicare's expense. *See* 42 U.S.C. § 1320f(a) (establishing the "Drug Price Negotiation Program"); *id.* § 1320f-1(b), (d), (e) (specifying which drugs are eligible for negotiation). For the first time, Medicare will be able to decide how much it is willing to pay for certain prescription drugs it covers—just as it has long determined how much it will reimburse doctors, hospitals, and other providers for medical services provided to Medicare beneficiaries.

Unsurprisingly, drug manufacturers—which have long profited from unrestricted growth in Medicare's prescription drug payments—lobbied hard against legislative efforts to introduce market discipline by giving the Secretary a seat at the negotiating table. And now that their lobbying failed, pharmaceutical companies and interest groups have repackaged their policy disagreements as lawsuits, filing complaints around the country challenging the statute on its face. This lawsuit, brought by Plaintiff Novartis Pharmaceuticals Corporation, largely rehashes the same legal theories offered by the other manufacturers. And it fails for the same reasons as the others.

As another district court recently recognized, Congress's authorization for the Secretary to negotiate Medicare prices "cannot be considered a constitutional violation" because drug manufacturers "are not legally compelled to participate in the [Negotiation] Program . . . or in Medicare generally." *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, — F. Supp. 3d —, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (*Chamber*). "[P]harmaceutical manufacturers who do not wish to" make their drugs available at negotiated prices can "opt out" by, for example, withdrawing from the Medicare and Medicaid markets or by divesting their interests in the drugs subject to negotiation before 2026, when any negotiated prices would first take effect. *Id.* The Negotiation Program—like Medicare more broadly—is thus "a completely voluntary" undertaking. *Id.* So while Plaintiff may be dissatisfied with the conditions Congress imposed on future Medicare spending, Plaintiff is neither compelled to surrender any property in violation of the Fifth Amendment nor required to speak in violation of the First.

Plaintiff's constitutional arguments fail in other respects, too. The company's theory that the Negotiation Program effects a "*physical*" taking of its property is untenable under the very Supreme Court cases that Plaintiff invokes. Pl.'s Mem. in Supp. of Mot. for Summ. J. at 1, ECF No. 18 (Pl.'s Br.) (emphasis added). Those cases emphasize "the settled difference in [the Supreme Court's] takings jurisprudence between" the government taking physical control of property and merely regulating its sale. *Horne v. Dep't of Agric.*, 576 U.S. 350, 362 (2015). But the IRA does not authorize the government to requisition a manufacturer's drugs or other property. Nor does the

IRA require a manufacturer to relinquish any drug it does not wish to sell. Plaintiff's physical-taking theory—the only taking theory it posits—therefore fails outright.

Similar errors infect Plaintiff's First Amendment arguments. Contrary to Plaintiff's assertions, neither the agreements that manufacturers have already signed with the Centers for Medicare & Medicaid Services (CMS) nor any other component of the Negotiation Program requires a manufacturer to adopt any government message. Indeed, those agreements do not require manufacturers to express any views at all. Those instruments are purely commercial arrangements that pertain solely to the prices at which manufacturers may choose to sell selected drugs to Medicare beneficiaries, using statutory language that ensures the signatories share a common understanding of the agreements' terms. And Plaintiff's unfounded fears about how those agreements might be perceived by the public do not justify abrogating decades of First Amendment case law in favor of a new—and limitless—presumption of First Amendment expression in every commercial act.

As to Plaintiff's Eighth Amendment challenge to the IRA's excise tax, the Court should dismiss that claim for lack of subject-matter jurisdiction. The claim is not redressable—and Plaintiff therefore lacks Article III standing—because no defendant in this lawsuit is empowered to enforce the tax that Plaintiff seeks to enjoin and have declared unconstitutional. Plaintiff's claim is also barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a), which prohibits any "suit for the purpose of restraining the assessment or collection of any tax," and by the tax exception to the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201(a), which prohibits issuance of declaratory judgments "with respect to Federal taxes." For both AIA and DJA purposes, a "tax"

is an exaction that Congress has labeled as such, and Congress has unambiguously described the section 5000D excise tax as a "tax." Because Plaintiff asks this Court to preemptively enjoin that tax and declare it unconstitutional, the tax claim must be dismissed for lack of subject-matter jurisdiction.

The tax claim would also fail on the merits. The excise tax does not violate the Eighth Amendment because it is neither a "fine" nor "excessive." Neither the Supreme Court nor, to Defendants' knowledge, any other court has ever held that a tax—let alone one that, like the one here, lacks any connection to a criminal offense—was a fine for Excessive Fines Clause purposes. And even if the tax were deemed a fine, it would not be a grossly disproportionate one, as the excise tax is proportional to the harm to the fisc and within the range of other constitutionally permissible exactions.

In creating the Negotiation Program, Congress exercised its constitutional prerogative to ensure that federal funds are spent according to its view of the "general Welfare." U.S. Const. art. I, § 8, cl. 1. Plaintiff's objections to that program are no more than "a dispute with the policy choices" made by Congress masquerading as constitutional theory. *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009). Rather than arguing against established precedent, the "better course of action is to seek redress through the . . . political process." *Id.* Plaintiff is not entitled to judicial relief.

BACKGROUND

I. Medicare and the IRA's Drug Negotiation Program

A. Medicare is a federal program that pays for covered healthcare services of qualified beneficiaries as well as for prescription drugs. *See generally* 42 U.S.C. §§ 1395 *et seq*. The Medicare statute encompasses several "Parts," which set forth the terms by

which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). "Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019) (internal quotation marks omitted). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *U.S. ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. §§ 1395w-101 *et seq*. Prior to the IRA, Congress had not granted the Secretary of Health and Human Services (HHS) authority to negotiate directly with drug manufacturers for the costs of covered medications under Medicare. To the contrary, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i).

Although this model was relatively economical at first, it has contributed to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No.

116-324, pt. II, at 37 (2019). Generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie – Humira and Imbruvica* 36 (May 2021), https://perma.cc/9L42-VRBK. And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2020), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, which undermines the program's premise of using market competition to reduce prices for beneficiaries and taxpayers. *Id.* at 120. Because of how cost-sharing and premiums function under the Part B and Part D programs, high drug costs also increase out-of-pocket payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001–11003, 136 Stat. 1818 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, acting through CMS, to establish the Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those that have the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition). *See* 42 U.S.C. §§ 1320f *et seq*. The Negotiation Program applies only to the prices Medicare pays for drugs that it covers; the statute regulates neither the prices

manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of negotiation-eligible drugs; the agency is then to select up to 10 such drugs for negotiation for price applicability year 2026, up to 15 for price applicability years 2027 and 2028, and up to 20 for price applicability year 2029 and subsequent years. *Id.* § 1320f-1(a)–(b). After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. Congress required CMS to consider numerous categories of information when formulating offers during the course of those negotiations, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs, (2) current "costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings to the American people, Congress imposed a "ceiling for [the] maximum fair price," which it tied to specified pricing data for the selected drugs. *Id.* § 1320f-3(c). But Congress also directed CMS to "aim[] to achieve the lowest maximum fair price" that it can persuade manufacturers to accept. *Id.* § 1320f-3(b)(1).

CMS will sign agreements to negotiate prices for selected drugs with willing manufacturers. *Id.* § 1320f-2. If those negotiations prove successful, a manufacturer will then sign an addendum agreement to provide Medicare beneficiaries access to the negotiated price for the drug. *Id.* A manufacturer that does not wish to sign such an

agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling its drugs to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales. 26 U.S.C. § 5000D. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* 131–32 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Or it can withdraw from the Medicare and Medicaid programs—in which case it will incur no excise tax and no other liability. *See id.* at 33–34, 120–21, 129–31; *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)(1)).

These conditions parallel those that Congress has long attached to other government healthcare programs. For example, Congress has long required that any drug manufacturer wishing to participate in Medicaid enter into agreements with the Secretary of Veterans Affairs (VA)—agreements that give the VA, the Department of Defense, the Public Health Service, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceilings. *See* 38 U.S.C. § 8126(a)–(h). Like those statutory provisions, the Negotiation Program thus gives manufacturers a choice: they can sell their products at prices the government is willing to pay, or they can take their business elsewhere.

II. Implementation of the Negotiation Program

Although the IRA provides a wealth of criteria and detail regarding the selection of drugs, the negotiation process, and the requirements of any agreement, Congress also recognized that implementing a new program of such complexity would require

numerous operational decisions within the new statutory framework. Accordingly, Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and soliciting public input. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* (Mar. 15, 2023), https://perma.cc/8X4K-CVD8. After considering more than 7,500 public comments "representing a wide range of views," CMS published the Revised Guidance on June 30, 2023. Revised Guidance at 1–2.

The Revised Guidance describes several aspects of the Negotiation Program for initial price applicability year 2026, including information about (1) the methodologies by which CMS selected drugs for negotiation; (2) the negotiation process, including the types of data that CMS will consider, the procedures for exchanges of offers and counteroffers, and the public explanations CMS will provide for negotiated prices; and (3) the procedures for manufacturers to follow if they decide at any point not to participate. *Id.* at 2–8. On that last point, the Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 33–34. The guidance also notes that manufacturers that wish to remain in the Medicare and Medicaid programs but do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 131–32.

The Treasury Department and the Internal Revenue Service (IRS) have issued a separate notice outlining how they interpret the IRA's excise-tax provision. *See* IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice). As that notice explains, Treasury intends to propose regulations specifying that the tax provided for in 26 U.S.C. § 5000D would be imposed on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals *under the terms of Medicare*"—*i.e.*, only those drugs dispensed, furnished, or administered to Medicare beneficiaries. *Id.* § 3.01 (emphasis added). The notice further provides that, consistent with Treasury's pre-existing regulations applicable to certain other excise taxes, "[w]hen no separate charge is made as to the § 5000D tax on the invoice or records pertaining to the sale of a designated drug, it will be presumed that the amount charged for the designated drug includes the proper amount of § 5000D tax and the price of the designated drug." *Id.* § 3.02.

Treasury's notice confirms that, "if a manufacturer charges a purchaser $100 for a designated drug during the first 90 days in a statutory period and does not make a separate charge for the § 5000D tax, $65 is allocated to the § 5000D tax and $35 is allocated to the price of the designated drug." *Id.* Accordingly, after 271 days, $95 is allocated to the section 5000D tax and $5 is allocated to the price of the designated drug. Thus, the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95% (not 1900%).[1] This interpretation is effective immediately; as the

[1] This result flows from the statutory formula for the tax amount specified in 26 U.S.C. § 5000D(a), (d).

notice explains, "[u]ntil the Treasury Department and the IRS issue further guidance, taxpayers may rely on" the interpretation the agency has articulated. *Id.* § 4.

The primary manufacturers of all 10 selected drugs for the first negotiation cycle, including Plaintiff, have now executed agreements to negotiate. *See* CMS, Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026 (Oct. 3, 2023), https://perma.cc/7R6M-ENEP. Under the schedule set by Congress, negotiations are to conclude by August 1, 2024. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b); *see* Revised Guidance at 91–92 (statutory timetable). Any agreed-upon prices for the selected drugs will take effect on January 1, 2026, about two years from now. 42 U.S.C. §§ 1320f(b), 1320f-2(a); Revised Guidance at 92.

III. Related Litigation

Prior to the deadline to execute negotiation agreements with CMS, drug manufacturers and interest groups filed multiple suits across the country challenging the constitutionality of the Negotiation Program. *See Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C. filed June 6, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio filed June 9, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. filed June 21, 2023); *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. filed June 16, 2023); *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-1103 (D. Conn. filed Aug. 18, 2023); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. filed Aug. 25, 2023); *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. filed Sept. 29, 2023).

The plaintiffs in one such case—brought by the U.S. Chamber of Commerce and its local affiliates—sought a preliminary injunction "to prevent the implementation

of [the] Program." *Chamber*, 2023 WL 6378423, at * 1. In doing so, the plaintiffs argued that the Negotiation Program was akin to utility regulations and would "yield confiscatory rates" in violation of the Fifth Amendment's Due Process Clause. *Id.* at *11. The court disagreed. Those claims failed "as a matter of law," the court concluded, because manufacturers are "not legally compelled to participate in the [Negotiation] Program." *Id.* As a result, the "Program's eventual 'maximum fair price' cannot be considered confiscatory because pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out." *Id.* The court thus denied the plaintiffs' motion. *Id.* at *14. The plaintiffs did not appeal that decision.

ARGUMENT

I. The Negotiation Program Is Not a Taking Because Participation Is Voluntary

Plaintiff's Takings Clause challenge follows a familiar playbook. Hospitals, nursing homes, and other providers have, for decades, raised similar arguments against other limits on Medicare reimbursements—and courts have, for decades, rejected such claims. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1276, 1279–80 (11th Cir. 2014) (collecting cases); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). The "law established" in those cases "is clear": because "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice," "the consequences of that participation cannot be considered a constitutional violation." *Chamber*, 2023 WL 6378423, at *11. And this principle, as the *Chamber* court correctly held, applies equally to the Negotiation Program. *Id.*

Neither the IRA nor any other part of Medicare "legally compel[s]" manufacturers to negotiate with CMS or to sell their drugs to Medicare beneficiaries. *Id.* "[P]harmaceutical manufacturers who do not wish to participate in the Program have the ability . . . to opt out" in several ways. *Id.* Like other Medicare reimbursement limits, the voluntary Negotiation Program thus reflects a valid exercise of Congress's constitutional authority to control the government's spending as a market participant—and raises no Takings Clause concerns.

A. The Negotiation Program does not compel participation

The Takings Clause of the Fifth Amendment prohibits the taking of private property for public use without just compensation. U.S. Const. amend. V. But it is well established that a "property owner must be *legally compelled* to engage in price-regulated activity for regulations to" impugn a property interest that the Fifth Amendment protects. *Garelick*, 987 F.2d at 916 (emphasis added); *see, e.g.*, *Bowles v. Willingham*, 321 U.S. 503, 517–18 (1944) (rent controls do not constitute prohibited taking because statute did not require landlords to offer their apartments for rent). When an entity "voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no" deprivation of property. *Garelick*, 987 F.2d at 916 (collecting cases); *see Franklin Mem'l Hosp.*, 575 F.3d at 129 ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."). And that is the case with limits on Medicare spending, like the kind Congress sought to achieve with the Negotiation Program. *See Chamber*, 2023 WL 6378423, at *11.

As courts have repeatedly explained, "participation in the Medicare program is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *see Baptist Hosp. E. v. Sec'y of HHS*, 802 F.2d 860, 869–70 (6th Cir. 1986); *Baker Cnty.*, 763 F.3d at 1279–80; *Garelick*, 987 F.2d at 917; *see generally Chamber*, 2023 WL 6378423, at *11 (discussing this precedent). Unlike public utilities, which "generally are compelled" by statute "to employ their property to provide services to the public," no statutory provision *requires* entities to participate in Medicare or to sell their property. *Garelick*, 987 F.2d at 916. So, whether confronting regulations limiting physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal: entities are not required to serve Medicare beneficiaries, and thus the government deprives them of no property interest for purposes of the Fifth Amendment when it imposes caps on the amount the government will reimburse. *Baptist Hosp.*, 802 F.2d at 869–70; *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (no taking because plaintiff "voluntarily chose to participate in the Medicare hospice program"); *Baker Cnty.*, 763 F.3d at 1279–80 (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for an obligation it voluntarily undertook . . . when it opted into Medicare"); *Franklin Mem'l Hosp.*, 575 F.3d at 129–30; *Garelick*, 987 F.2d at 916–19; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986). If a provider dislikes the conditions offered by the government, it can simply withdraw from the program. *Baptist Hosp.*, 802 F.2d at 869–70. There is no legal compulsion to participate.

The Negotiation Program is no different. *See Chamber*, 2023 WL 6378423, at *11. The IRA regulates neither the prices manufacturers may charge for drugs generally nor

the conduct of manufacturers that elect not to participate in Medicare and Medicaid. *See, e.g.*, 42 U.S.C. § 1320f-1(b), (d). Rather, Congress established the Negotiation Program in an effort to reduce how much Medicare pays for selected drugs provided to Medicare beneficiaries. *See id.* § 1320f-2(a)(2). As CMS noted, "the IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation" in Medicare and Medicaid. Revised Guidance at 120; *see also* 26 U.S.C. § 5000D(c)(1) (providing that tax consequences apply only if the manufacturer continues to participate in Medicare and Medicaid). Drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices can avoid doing so by withdrawing from the Medicare and Medicaid programs. *See Chamber*, 2023 WL 6378423, at *11; *see also* Revised Guidance at 33–34, 120–21, 129–31.[2] Alternatively, a manufacturer can divest its interest in the selected drug to a separate entity—or otherwise stop selling it to Medicare beneficiaries, either permanently or temporarily. Revised Guidance at 131–32.

Thus, contrary to Plaintiff's claims, manufacturers "are not legally compelled to participate in the Program," nor forced to make sales they don't want to make. *Chamber*, 2023 WL 6378423, at *11. Unlike laws requiring utilities to serve the public, the IRA does not "compel[] [manufacturers] to employ their property to provide [drugs] to" Medicare beneficiaries—at any price. *Garelick*, 987 F.2d at 916. Rather, a manufacturer

[2] Recognizing the viability of this option, some manufacturers previously stated that they might do so. *See* Zachary Brennan, *IRA side effect: Pharma companies will increasingly skip Medicare altogether, Lilly CEO says*, Endpoint News (June 14, 2023), https://perma.cc/ZWJ4-6EXF.

of a selected drug is required to provide "access" to negotiated prices *only* if it *chooses* to participate in Medicare and make its drugs available for Medicare coverage. As courts have explained in rejecting Fifth Amendment challenges to other Medicare conditions, "[i]f any provider fears that its participation [in the program] will drive it to insolvency, it may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869–70. That choice is the manufacturer's to make.

B. Manufacturers have adequate opportunity to withdraw from the program

Attempting to evade this settled precedent, Plaintiff suggests that the IRA makes it impossible for manufacturers to avoid providing Medicare beneficiaries access to the selected drug without incurring a sizeable tax or a penalty. Pl.'s Br. at 15–16. Plaintiff has not indicated that it wishes to withdraw from the Negotiation Program or from Medicare and Medicaid; to the contrary, it has signed an agreement to negotiate. *See* Manufacturer Agreements at 1; Pl.'s Ex. E, ECF No. 18-7. So the company's complaints about the process for withdrawal are purely academic. But regardless, these arguments fail because Plaintiff misunderstands the IRA's terms.

Section 11003 of the IRA provides that manufacturers will incur no tax if they cease participating in Medicare and Medicaid prior to the statutory deadline to enter into an agreement to negotiate—or, if they have initially agreed to negotiate (as Plaintiff has), prior to the statutory deadline to enter into a final pricing agreement with CMS. *See* 26 U.S.C. § 5000D(b)(1)–(2) (defining periods when tax would take effect); *id.* § 5000D(c)(1)(A)(i)–(ii) (providing that the excise tax will be suspended "beginning on the first date on which" "none of the drugs of the manufacturer" are covered by

Medicare).[3] The Social Security Act (SSA) provides that the relevant Medicare-participation agreements can be terminated by CMS in 30 days for "good cause." *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on these provisions, the Revised Guidance explains that if a "[m]anufacturer determines . . . that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice," CMS will treat that determination as providing "good cause to terminate the . . . Manufacturer's agreement(s) . . . and thus facilitate an expedited" termination in 30 days. Revised Guidance at 130. As a result, "any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting the notice and termination requests . . . 30 days in advance of the date that excise tax liability otherwise may begin to accrue." *Id.* at 33–34.

That timeline provides manufacturers flexibility to "opt out" of the Negotiation Program. *Chamber*, 2023 WL 6378423, at *11. Manufacturers of the first 10 selected drugs had 34 days to decide whether they wanted to negotiate with CMS before any tax liability (for selling the drug to Medicare without signing an agreement to negotiate) could be triggered. *See* 42 U.S.C. § 1320f(d)(1) (requiring first list of drugs for negotiation to be published by September 1, 2023);[4] 26 U.S.C. § 5000D(b)(1) (tax triggered on October 2, 2023, absent manufacturer signing agreement to negotiate). Plaintiff, along with the manufacturers of all the other selected drugs, signed an agreement to negotiate. *See* Manufacturer Agreements at 1. Manufacturers will know

[3] Section 5000D(c) also conditions suspension of the tax on a manufacturer giving notice of termination of its drug rebate agreement under Medicaid. 26 U.S.C. § 5000D(c)(2).

[4] The list was published early, on August 29, 2023.

how those negotiations are going far in advance of August 2, 2024, when they could first be exposed to tax liability if they have not signed a final price agreement. *See* 26 U.S.C. § 5000D(b)(2). And if a manufacturer signs a final price agreement before the statutory deadline, there will still be *at least 17 months* before January 1, 2026, when any negotiated prices would first take effect—and any civil penalty (but no tax) could even possibly be triggered. 42 U.S.C. § 1320f-6(a) (providing for civil monetary penalties for failing to honor agreement). During this period, the manufacturer can (with 30 days' notice) withdraw from Medicare and Medicaid or divest its interest in the selected drug. Revised Guidance at 129–32. In this way, a "manufacturer that has entered into an Agreement . . . retain[s] the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability." *Id.* at 34.

Plaintiff fails to grapple with these various options. *Compare, e.g.*, Pl.'s Br. at 14 n.3 (contending that "the only way a manufacturer could avoid having its own selected drug dispensed to Medicare beneficiaries would be to divest its interests in the drug"), *with id.* at 18 (appearing to concede that it could "avoid the [Negotiation Program] by withdrawing from Medicare"). Even putting aside CMS's guidance, Plaintiff overlooks the 28-month period between a drug's selection and the January 2026 effective date for any negotiated prices. This delay gives a manufacturer ample time to notice its termination of the relevant Medicare agreements (something it could do even while otherwise engaged in negotiations) and have that termination take effect. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (a "manufacturer may terminate an agreement under this section for any reason," and "if the termination occurs before January 30 of a plan year" it shall become effective "as of the day after the end of the plan year").

Plaintiff separately complains that withdrawing from Medicare is "onerous" because it would prove financially ruinous for Plaintiff and would leave Medicare beneficiaries without much-needed drug products. Pl.'s Br. at 20–21. But courts have, for decades, held that economic or other practical "hardship is not equivalent to legal compulsion for purposes of [a] takings analysis." *Garelick*, 987 F.2d at 917; *see also St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that the decision to participate in the program "is nonetheless voluntary." *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). This precedent makes clear that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Chamber*, 2023 WL 6378423, at *11 (collecting cases); *see Baker Cnty.*, 763 F.3d at 1280. And, to the extent that the government likewise has an interest in manufacturers continuing to participate in Medicare, Pl.'s Br. at 21, that only confirms that manufacturers have leverage in negotiating prices with CMS. Just as defense contractors that derive a substantial portion of their revenues from the Department of Defense are free to refuse contracts they find unprofitable and to leverage the importance of their products to the government to drive a better bargain, drug manufacturers can walk away from the Negotiation Program—even if doing so comes at a cost.

In short, Plaintiff is wrong to claim that Congress did not give manufacturers a genuine choice whether to sell their drugs to Medicare at negotiated prices. Plaintiff's choice "to opt out" of the Negotiation Program is real. *Chamber*, 2023 WL 6378423, at *11.

C. The Negotiation Program is a proper condition on voluntary participation in federal healthcare programs

Plaintiff next seeks to undermine the voluntariness of the Negotiation Program by analogizing to inapposite cases analyzing government demands for property in the context of *regulatory* regimes. Pl.'s Br. at 22–24. Plaintiff interprets these cases to suggest that participation in the Negotiation Program could be voluntary only if it came in "exchange" for an appropriate "benefit"—something that Plaintiff insists is absent here because the benefit (Medicare coverage) is something they already enjoy. *Id.* at 23–24. But Plaintiff fails to grasp the difference between regulatory and *spending* programs, and it fails to appreciate that conditions that Congress attaches to the latter are subject to a fundamentally different form of constitutional review. In any event, the Negotiation Program withstands scrutiny even under Plaintiff's erroneous analytical framework.

1. Plaintiff incorrectly analyzes the Negotiation Program as a regulatory condition

The defining feature of the cases on which Plaintiff relies is that they analyzed conditions that the government imposed as part of an obligatory legal framework, which parties could not readily avoid or exit. *See generally* Pl.'s Br. at 18–23. In *Ruckelshaus v. Monsanto Co.*, for example, manufacturers had no choice but to surrender their proprietary data if they wished to sell their pesticides to private customers under

an environmental regulatory regime. 467 U.S. 986, 1007 (1984). The Court saw the surrender of property not as a taking or unconstitutional condition but rather as a voluntary exchange for a license to sell chemicals, because that license was not something the government was otherwise required to provide. *See id.* In *Horne*, raisin growers had to physically surrender a portion of their crop to the government as part of an agricultural regulatory program if they wished to grow and sell raisins on open markets—and, as the Court explained, "[s]elling produce in interstate commerce, although certainly subject to reasonable government regulation, is . . . not a special governmental benefit." 576 U.S. at 366. In both circumstances, the question of whether the demand for property was part of an exchange for a non-illusory benefit (and therefore not a taking) arose only because the regulated parties could not avoid the government's property demand without "ceasing to" sell their product to *anyone*. *Id.* at 365; *accord Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 439 n.17 (1982).

Similar reasoning animated the D.C. Circuit's decision in *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023). *See* Pl.'s Br. at 23. There, the D.C. Circuit confronted a takings challenge to a provision of the Copyright Act requiring "the owner of the copyright in a work [to] deposit two copies of the work with the Library of Congress" or pay a fine. *Valancourt*, 82 F.4th at 1226. The panel determined that, under the "particular circumstances" before the court, this requirement was mandatory and inescapable, arising automatically upon publication of the work. *Id.* at 1239. The D.C. Circuit thus concluded that the condition could not be justified as part of a "voluntary exchange for a governmental benefit" because "the purported 'benefit' [was] illusory." *Id.* at 1232. As the panel explained, "copyright owners receive[d] no

additional benefit for the works they forfeit[ed]" because the "[m]andatory deposit is not required to secure the benefits of copyright." *Id.* Absent at least some benefit, the demand constituted a physical taking of plaintiffs' books. *Id.* at 1235.[5]

This reasoning does not apply, however, when Congress acts pursuant to its *spending* powers to set terms on which the government will buy products. In this circumstance, the government is neither restricting entities from engaging in interstate commerce nor burdening their ability to sell goods to private buyers. Rather, these types of conditions are inherently "voluntary"—and do not compel entities to surrender property—because there is no "right (or requirement)" to conduct business with the government in the first instance. *Chamber*, 2023 WL 6378423, at *11; *see, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."). Unlike the raisins in *Horne*, Medicare funds are property that "belong[s] to the State," and manufacturers have no right in that property "other than such as the state may permit [them] to acquire." *Horne*, 576 U.S. at 366–67 (internal quotation marks omitted). "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980); *see also Perkins v. Lukens*

[5] The same was true in *Union Pacific Railroad Co. v. Public Service Commission*, 248 U.S. 67 (1918). *See* Pl.'s Br. at 19. Like *Monsanto* and *Horne*, that case involved a regime that parties could not readily exit—so the plaintiff was involuntarily subject to the government's property demands. *See Union Pacific*, 248 U.S. at 67 (plaintiff subject to statutory prohibition against issuance of a bond unless the prohibition was waived by a state commission). Similarly, in *Tenoco Oil v. Department of Consumer Affairs.*, the plaintiffs challenged a price regulation that applied to *all* wholesale gasoline sales. *See* 876 F.2d 1013, 1014 (1st Cir. 1989) (vacating injunction against price regulation because claims were "not yet ripe"); *see* Pl.'s Br. at 19.

Steel Co., 310 U.S. 113, 127 (1940) (government has authority to "determine those with whom it will deal"); *J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts").

Unsurprisingly, given this distinction between demands for property as part of a regulatory regime and conditions that Congress sets for participation in federal spending programs, courts have not employed Plaintiff's proposed framework to evaluate takings challenges to Medicare or Medicaid conditions. *See supra* at 14 (collecting cases). Rather, courts have rejected such challenges on the threshold ground that "participation in the Medicare program is a voluntary undertaking"—and have not further analyzed the propriety of the condition. *Livingston Care Ctr.*, 934 F.2d at 720; *see Chamber*, 2023 WL 6378423, at *11 (discussing this precedent).

This approach makes sense. "Unlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily, Spending Clause legislation operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions." *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022) (internal quotation marks omitted). "[I]f a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013). There is therefore no need to consider whether a party obtained a separate benefit to determine that the government's conditions are part of a voluntary exchange. *Contra* Pl.'s Br. at 22.

The Negotiation Program, of course, *is* voluntary, in the way that all Medicare and Medicaid conditions are—and in a way that the conditions in regulatory programs

like those at issue in *Horne* and the other cases Plaintiff cites were not. Drug manufacturers' ability to make commercial sales is not conditioned on them complying with the Negotiation Program. They can continue selling their drugs to everyone but the government and be free of the Negotiation Program's terms. *See Chamber*, 2023 WL 6378423, at *11. This raises no Fifth Amendment takings concerns because Plaintiff "do[es] not have a property interest in a particular reimbursement rate" from Medicare. *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013); *see Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996).

2. The Negotiation Program withstands scrutiny even under Plaintiff's erroneous framing

In any event, the Negotiation Program would still survive scrutiny under Plaintiff's framing—even if it were incorrectly analyzed as part of a typical regulatory regime. As the D.C. Circuit observed in *Valancourt*, "any forfeiture of property might arguably be voluntary" where there is "a simple, seamless, and transparent way to opt out of" the regulatory regime in which the demand for property is made. 82 F.4th at 1235. The problem in *Valancourt* was that no exit option was "cognizable to copyright owners": "no statute, regulation, or guidance" indicated that Valancourt could relinquish its copyright in lieu of depositing books by, for example, "simply disavowing its copyrights." *Id.* at 1235–36. The agency instead "implied that Valancourt was obligated to deposit regardless of any voluntary action it took." *Id.* at 1236.

The opposite is true here. As the *Chamber* court recognized, manufacturers can avoid the Negotiation Program's requirements by, among other things, divesting their interest in the selected drug or withdrawing from Medicare and Medicaid by terminating

their participation agreements. *See* 2023 WL 6378423, at *11. Doing so is straightforward. A manufacturer need only notify CMS of its intent to withdraw from the relevant agreements "30 days in advance of the date that excise tax liability otherwise may begin to accrue." Revised Guidance at 33–34.[6] As explained, *supra* at 17, this course is clearly described in the Revised Guidance, which relies on the authority provided in the SSA. *See id.* at 130; *see generally* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). So, unlike Valancourt, manufacturers have a "cognizable" notice of the withdrawal options from a formal "guidance." 82 F.4th at 1235–36. There is no dispute that Plaintiff is now well aware of these options and thus its ability to "opt out of Medicare entirely." *Chamber*, 2023 WL 6378423, at *11.

In addition to disregarding its withdrawal options, Plaintiff complains that it could not have anticipated the Negotiation Program when it first chose to participate in Medicare and Medicaid, which now account for the majority of the market in which Plaintiff makes its sales. *See* Pl.'s Br. at 24. But, as explained, "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Chamber*, 2023 WL 6378423, at *11 (collecting cases). This is true regardless of whether the condition is new to the program in which Plaintiff has been participating. *See* 42 U.S.C. § 1304 (noting that Congress reserves the right to change Medicare terms). Where, as here, an exit option is available, Plaintiff's decision not to pursue it—for whatever reason—is itself an indication that, going forward, Plaintiff consents to the condition imposed.

[6] Alternatively, as explained, a manufacturer can transfer ownership of the drug. *See* Revised Guidance at 131–32.

Plaintiff also wrongly contends that the Negotiation Program is not a proper condition—*i.e.*, one for which there can be any exchange—because not all participants in Medicare have drugs selected for the Program. *See* Pl.'s Br. at 22. As an initial matter, although only a certain number of drugs are selected each year, *all* drug manufacturers that choose to participate in Medicare agree to the program's conditions, which now include being subject to the Negotiation Program's selection criteria—whether or not they manufacture drugs that meet those criteria in any given year. *See generally* 42 U.S.C. § 1320f-1. Plaintiff does not cite any authority suggesting that a valid condition must produce equivalent results for all participants. Nor does Plaintiff cite any authority suggesting that conditions on government spending must be applied to all program participants to pass constitutional muster. Absent an equal-protection claim—which Plaintiff has not asserted here and which would plainly fail in any event—this argument has no legal foundation.

Moreover, Plaintiff's claims to the contrary notwithstanding, it is worth noting that manufacturers do receive "additional benefits" in exchange for their agreement to a negotiated price for their selected drugs. *Valancourt*, 82 F.4th at 1233. The IRA provides that, in exchange for reaching an agreement with CMS as to the maximum fair price for a selected drug, a manufacturer is guaranteed formulary inclusion by all Medicare Part D plans for that drug. 42 U.S.C. § 1395w–104(b)(3)(I)(i). Plaintiff may choose to accept this benefit, or it may choose to exit the Medicare and Medicaid programs. The choice is Plaintiff's, and the voluntary nature of that choice defeats Plaintiff's takings claim.

3. Plaintiff's alternative unconstitutional-conditions argument is inapposite

Many of the same reasons likewise defeat Plaintiff's attempt to undermine the Negotiation Program by invoking the test articulated by the Supreme Court in *Nollan v. California Coastal Commission* and *Dolan v. City of Tigard*, which asks whether an exaction sought by the government is "rough[ly] proportiona[l]" to the benefit being sought by a property owner. Pl.'s Br. at 25 (quoting *Dolan*, 512 U.S. 374, 391 (1994)); *see Nollan*, 483 U.S. 825, 834–37 (1987). Contrary to Plaintiff's suggestion, these cases do not set forth a general unconstitutional-conditions framework. Rather, the Supreme Court has made clear that the *Nollan* and *Dolan* test is reserved for "'special application' of the doctrine to . . . land-use permits." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (quoting *Lingle v. Chevron USA Inc.*, 544 U.S. 528, 538 (2005)). That is for good reason: permit applicants are "especially vulnerable" to the government's demands "because the government often has broad discretion to deny a permit that is worth far more than property it would like to take." *Koontz*, 570 U.S. at 604–05. Determining that a land-use exaction is "proportional[]" to the governmental benefit thus ensures that the condition is part of a voluntary exchange. *Id.* at 605; *see also Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (explaining this framework).

No such proxy test is necessary or appropriate where Congress merely sets the terms on which the government will do business—business to which the party has no freestanding entitlement and that it can freely decline. Courts do not, for example, superintend government contracts to ensure that they provide contractors sufficient compensation or benefit to avoid a Fifth Amendment taking. *See, e.g.*, *St. Christopher*

Assocs., L.P. v. United States, 511 F.3d 1376, 1385 (Fed. Cir. 2008) ("In general, takings claims do not arise under a government contract because . . . the government is acting in its proprietary rather than its sovereign capacity" and any right to compensation has "been voluntarily created" (internal quotation marks omitted)). Plaintiff may be unhappy that Congress created the Negotiation Program as a condition on its future Medicare and Medicaid participation, but that dissatisfaction does not render the condition constitutionally improper.

* * *

At bottom, Plaintiff cannot establish that the Negotiation Program is anything other than "completely voluntary." *Chamber*, 2023 WL 6378423, at *11. And because "there is no legal compulsion to" participate, "there can be no" Fifth Amendment violation. *Garelick*, 987 F.2d at 916.

II. The Negotiation Program Is Not a Physical Taking of Plaintiff's Drugs

Even setting aside the voluntary nature of the Negotiation Program—and the settled precedent rejecting Fifth Amendment challenges to Medicare reimbursement caps—Plaintiff's takings claim fails even as articulated. Plaintiff seeks to paint the Negotiation Program as a "classic, *per se*" taking—*i.e.*, physical taking—of its actual products, akin to the taking of raisins in *Horne*. Pl.'s Br. at 12–16. But the Negotiation Program in no way forces manufacturers to surrender their drugs—to the government or to anyone else—and thus cannot be construed as a "classic" or "physical" taking.

As the Supreme Court has explained, a "classic taking [is one] in which government directly appropriates private property or ousts the owner from his domain." *Lingle*, 544 U.S. at 539. With such takings, the owners "lose the entire 'bundle'

of property rights" in a way they do not through regulations. *Horne*, 576 U.S. at 361–62; *see Cedar Point*, 141 S. Ct. at 2074; *Lingle*, 544 U.S. at 539. So even where "a physical taking" and a "regulatory limit . . . may have the same economic impact," a "distinction flows naturally from the settled difference in [the Supreme Court's] takings jurisprudence between appropriation and regulation" that does not allow a court to equate the two. *Horne*, 576 U.S. at 362; *see also Cedar Point*, 141 S. Ct. at 2072 ("The essential question is . . . whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property.").

Here, there is no "physical appropriation" at all. *Cedar Point*, 141 S. Ct. at 2074. Unlike the Department of Agriculture in *Horne*, CMS will not "sen[d] trucks to [Plaintiff's] facility at eight o'clock one morning to" haul away pills. 576 U.S. at 356. And the IRA does not require manufacturers to provide "access" to their drugs against their will. *Contra* Pl.'s Br. at 13. Neither the formulary provision Plaintiff cites—which defines circumstances in which insurance plans contracting with Medicare are to provide coverage for the selected drugs under Part D, 42 U.S.C. § 1395w-104(b)(3)(I)[7]—nor anything else in the IRA requires manufacturers to *make sales* in the first instance. *Contra* Pl.'s Br. at 14.

What the IRA provides, instead, is that a manufacturer that signs an agreement for a negotiated price will be expected "to provide access *to such price*" for sales to

[7] As explained above, this statutory provision actually offers a *benefit* to participating manufacturers. *See supra* at 26. This provision does not require manufacturers to make sales—it merely states that insurance providers shall cover the drugs that manufacturers do, in fact, agree to sell. *See* 42 U.S.C. § 1395w-104(b)(3)(I).

Medicare beneficiaries. 42 U.S.C. § 1320f-2(a)(1), (a)(3) (emphasis added). Rather than requiring manufacturers to give Medicare beneficiaries physical "access" to drugs, this provision merely establishes the prices at which any such sales *may* be made. *Cedar Point*, 141 S. Ct. at 2072. The "penalties" about which Plaintiff complains, Pl.'s Br. at 15, thus attach only if a manufacturer provides drugs to Medicare beneficiaries at prices above those negotiated with CMS. *See* 42 U.S.C. § 1320f-6(a) (penalties apply for failure to "provide access to a *price*" (emphasis added)). There is no penalty (or tax liability) for not *selling* the drugs in the first place. Plaintiff's physical taking argument therefore runs aground on the "settled difference in . . . takings jurisprudence between appropriation and regulation"—a distinction that the Supreme Court has relied on even when the two "may have the same economic impact." *Horne*, 576 U.S. at 362. And Plaintiff's efforts to conflate "access" to *prices* with "access" to *drugs*—by omitting critical parts of the statutory language, Pl.'s Br. at 13—betrays the conceptual problem with their takings theory writ large.

In any event, even if Congress *were* forcing manufacturers to sell their drugs or otherwise "compel[ing] [manufacturers] to employ their property to provide [drugs] to the public," that would (at worst) place those companies in a position similar to public "utilities." *Garelick*, 987 F.2d at 916. Yet the Supreme Court has not treated utility rate-setting as physical takings. *See, e.g.*, *Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467, 524–27 (2002); *see also Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307–15 (1989) (discussing evolution of takings jurisprudence with respect to public utilities). This makes sense: imposing limits on rates that utilities may charge customers does not deprive those utilities of the whole "bundle" of rights that are lost when the government physically

seizes or invades property. *E.g.*, *Horne*, 576 U.S. at 361. And the Supreme Court has rejected facial challenges to statutory utility rate-setting methodologies, explaining that "the general rule is that any question about the constitutionality of rate-setting is raised by rates, not methods." *Verizon*, 535 U.S. at 525. Plaintiff, of course, is not challenging any "particular, actual . . . rate" yet—nor can it do so. *Id.* at 524. The negotiation process is still in its early stages; the results of the negotiations are as yet unknown.[8]

This uncertainty would have foreclosed any attempt Plaintiff might have made to proceed under a regulatory taking theory. "Government regulation often 'curtails some potential for the use or economic exploitation of private property,' and 'not every destruction or injury to property by governmental action has been held to be a "taking" in the constitutional sense.'" *E. Enters. v. Apfel*, 524 U.S. 498, 523 (1998) (citations omitted). "In light of that understanding, the process for evaluating a regulation's constitutionality . . . is essentially ad hoc and fact intensive" and does not lend itself to broad categorical rules. *Id.*; *see Lingle*, 544 U.S. at 548. It is thus unsurprising that Plaintiff eschews a regulatory taking theory. *See* Pl.'s Br. at 16. But Plaintiff fares no better with the theory it has brought.

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[8] Plaintiff nonetheless asserts that the IRA necessarily "ensures a price well below the going market rate." Pl.'s Br. at 16. In addition to being incorrect as a categorical matter, this assertion is irrelevant. In the utility rate-setting context, courts do not look to market price as a measure of a taking. *See, e.g.*, *Duquesne Light*, 488 U.S. at 308 (noting the difficulty of analyzing what constitutes "just compensation . . . and what are the necessary elements in such an inquiry" (internal quotation marks omitted)). Instead, courts look to various factors related to investment-backed expectations—which depend on case-specific factors that are inimical to a facial challenge, and which Plaintiff does not even try to establish here. *See, e.g.*, *Verizon*, 535 U.S. at 524-27 (explaining the need to conduct a fact-intensive inquiry).

III. Plaintiff's First Amendment Claim Is Meritless Because the Negotiation Program Does Not Compel Manufacturers to Speak

Plaintiff's First Amendment claim fares no better. That challenge rests entirely on Plaintiff's erroneous contention that the agreements that manufacturers sign with CMS constitute "compelled" "speech" and thus violate the First Amendment. Pl.'s Br. at 27.

1. Signing an agreement with CMS is not speech, nor is it expressive conduct. And any "speech" that may ordinarily be implicated in the execution of a commercial contract "is plainly incidental to the . . . regulation of conduct" that the contract governs. *Rumsfeld v. Forum for Acad. & Inst. Rts., Inc.* (*FAIR*), 547 U.S. 47, 62 (2006). The regulation of conduct "has never been deemed an abridgment of freedom of speech . . . merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Id.* (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)). Medicare routinely uses agreements that health care providers or other entities sign to memorialize their voluntary acceptance of the terms for participation in various programs; those agreements do not signify providers' endorsement of, for example, the general fairness of the Medicare rate-setting process. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c). These agreements—memorializing manufacturers' acceptance of the terms for participation in the Negotiation Program—are no different.

Manufacturers that choose to sign agreements with CMS undertake a voluntary obligation to negotiate prices and, ultimately, to provide Medicare beneficiaries with access to the negotiated prices for the selected drugs that the manufacturers sell. *See*

Revised Guidance at 118–20; *see also* Pl.'s Ex. E. This does not implicate the First Amendment any more than "typical price regulation," which "would simply regulate the amount [of money] that a [manufacturer] could collect." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). As Plaintiff appears to recognize, *see* Pl.'s Br. at 28, such "ordinary price regulation does not implicate constitutionally protected speech," *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019) (citing *Expressions Hair Design*, 581 U.S. at 47); *see also Campbell v. Robb*, 162 F. App'x 460, 468 (6th Cir. 2006) (recognizing "the general principle that government retains its full power to regulate commercial transactions directly, despite elements of speech and association inherent in such transactions"). In the same way, because the request that participating manufacturers sign agreements "is imposed 'for reasons unrelated to the communication of ideas,'" that request does "not implicate the First Amendment." *Nicopure*, 944 F.3d at 291 (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001)); *see also Expressions Hair Design*, 581 U.S. at 47 (where a "law's effect on speech would be only incidental to its primary effect on conduct," the law is not a regulation of speech subject to First Amendment scrutiny).

A manufacturer's decision to sign the negotiation agreement "is not inherently expressive," *FAIR*, 547 U.S. at 64, which is "underscored by [the agreement's] bearing only on product price," *Nicopure*, 944 F.3d at 292, and ancillary program obligations. The terms of the agreement explicitly state what is already apparent: a manufacturer's signature constitutes neither an "endorsement of CMS' views" nor a representation of the manufacturers' views concerning the fairness of prices. *See* Pl.'s Ex. E at 4 (explaining that, by "signing this Agreement, the Manufacturer does not make any

statement regarding or endorsement of CMS' views"). There is no merit to Plaintiff's claim that the "disclaimer reinforces" its view that the contract suggests an endorsement of CMS's views. Pl.'s Br. at 46 n.17. The government, no less than a commercial party, is free to emphasize an already obvious point. Indeed, contracts do this routinely, often to ensure that the parties have a shared understanding of the contract's terms. So too here: the agreement uses statutory terms merely as a way of ensuring that the signatories share the same understanding of their respective obligations, and it explicitly emphasizes that the use of such terms serves this practical (and nonexpressive) purpose. Plaintiff cites no canon of construction supporting its view that a disclaimer has any expressive effect.

This commercial arrangement is nothing like the regulations challenged in the cases that Plaintiff cites. *See, e.g.*, *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 138 S. Ct. 2448, 2464 (2018) (holding that requiring public employees to pay union fees violated their free speech rights); *Wooley v. Maynard*, 430 U.S. 705, 707 (1977) (holding that state law requiring "noncommercial vehicles [to] bear license plates embossed with the state motto, 'Live Free or Die'" violated First Amendment); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 966–67 (9th Cir. 2009) (holding, in relevant part, that state law's labeling requirement for "violent video games" was unconstitutional compelled speech); Pl.'s Br. at 28, 32 & n.5. The agreement to negotiate does not require manufacturers "to utter or distribute speech bearing a particular message," *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994), or to say anything about any agreed-on prices. Nor does the agreement restrict manufacturers' ability to say whatever they wish about the Negotiation Program or to criticize CMS or the IRA.

A manufacturer may, of course, have numerous reasons for signing or not signing an agreement with CMS, and some of those reasons may pertain to views that it holds or wants to communicate to others. But a manufacturer's views regarding the IRA or negotiated prices "do[] not convert all regulation that affects access to [selected drugs] into speech restrictions subject to First Amendment scrutiny." *Nicopure*, 944 F.3d at 291. *Cf. City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989) ("It is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one's friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment."). Signing an agreement to negotiate "is simply not the same as forcing a student to pledge allegiance to the flag . . . or forcing a Jehovah's Witness to display a particular motto on his license plate . . . and it trivializes the freedom protected in [those circumstances] to suggest that it is." *FAIR*, 547 U.S. at 48 (citing *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943), and *Wooley v. Maynard*, 430 U.S. 705 (1977)).

2. Moreover, because the Negotiation Program is voluntary, it does not compel any manufacturer to sign an agreement—or to do anything at all. *Contra* Pl.'s Br. at 30. For the reasons explained above, Plaintiff's assertion that the manufacturer of a selected drug is "forced" to sign an agreement to negotiate, *id.* at 46, overlooks the various options the manufacturer has to exit or otherwise avoid the Negotiation Program, *see supra* Part I.B; *see also Chamber I*, 2023 WL 6378423, at *11. The First Amendment does not prohibit the government from giving a company the option to sign an agreement governing the terms of a program in which the company chooses to participate. *See, e.g.*, *FAIR*, 547 U.S. at 59 (noting that "Congress is free to attach reasonable and

unambiguous conditions to federal" funds without triggering First Amendment scrutiny (quoting *Grove City College v. Bell*, 465 U.S. 555, 575–76 (1984))). Just as manufacturers are not forced to sell drugs to Medicare, manufacturers are not forced to sign agreements to negotiate the prices of those drugs. So even if Plaintiff's "speech" were at issue here, that speech is not "compelled."

3. Plaintiff alternatively suggests that the invitation to sign a negotiation agreement violates the "unconstitutional conditions doctrine," Pl.'s Br. at 35—but this argument likewise fails at the threshold. Even if the agreements were expressive—which, again, they are not—the Supreme Court has long upheld conditions on speech that pertain to the nature of a government program. Where a program arises under the Spending Clause, Congress is free to attach "conditions that define the limits of the Government spending program—those that specify the activities Congress wants to subsidize." *Agency for Int'l Dev.*, 570 U.S. at 214; *see, e.g.*, *United States v. Am. Lib. Ass'n*, 539 U.S. 194, 212 (2003) (plurality opinion) (rejecting a claim by public libraries that conditioning funds for internet access on the libraries' installing filtering software violated their First Amendment rights, explaining that "[t]o the extent that libraries wish to offer unfiltered access, they are free to do so without federal assistance"); *Regan v. Taxation With Representation*, 461 U.S. 540, 546 (1983) (rejecting "the notion that First Amendment rights are somehow not fully realized unless they are subsidized by the State" (internal quotation marks omitted)). Conditions implicating speech may be suspect only where those conditions "seek to leverage funding to regulate speech outside the contours of the program itself." *Agency for Int'l Dev.*, 570 U.S. at 214–15.

Here, the supposed condition about which Plaintiff complains is the signing of an agreement to negotiate and, ultimately, a pricing agreement. Those voluntary agreements are the core mechanisms by which negotiations will proceed and the source of the enforceable obligation for manufacturers to provide selected drugs at negotiated prices. *See* Revised Guidance at 118–20. In this way, these agreements "define the [Negotiation] program and" do not "reach outside it." *Agency for Int'l Dev.*, 570 U.S. at 217. Because these agreements are simply "designed to ensure that the limits of the federal program are observed"—and that Medicare funds are "spent for the purposes for which they were authorized"—the opportunity to sign an agreement to participate in the Negotiation Program does not impose unconstitutional conditions on the use of federal funds. *Rust v. Sullivan*, 500 U.S. 173, 193, 196 (1991).

IV. The Court Lacks Subject-Matter Jurisdiction over Plaintiff's Meritless Excise-Tax Claim

A. The Court lacks jurisdiction over Plaintiff's excise-tax claim

As a threshold matter, Plaintiff's Eighth Amendment excise-tax claim should be dismissed because it runs afoul of two independent jurisdictional barriers. First, this claim is not redressable because Plaintiff has not sued the Department of the Treasury or the IRS—the only agencies empowered to enforce the tax that Plaintiff seeks to enjoin and have declared unconstitutional. Second, this claim is barred by the AIA and the tax exception to the DJA.[9]

[9] The Court may dismiss the claim on either of those grounds. *See Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007). Dismissal on the basis of the AIA would be more efficient, however, because Plaintiff cannot overcome the AIA by filing a new or revised complaint against the proper defendants.

1. Plaintiff's excise-tax claim is not redressable in this suit

Plaintiff lacks Article III standing to press its constitutional challenge to the excise tax. To show Article III standing, a plaintiff "bears the burden of establishing" that it has "suffered an injury in fact . . . that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998). Redressability must be established "for each claim that [plaintiff] press[es] and for each form of relief that [it] seek[s]." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021); *see also id.* ("[S]tanding is not dispensed in gross.").

Plaintiff's excise-tax claim cannot be redressed in this suit against HHS and CMS. *See Haaland v. Brackeen*, 599 U.S. 255, 292 (2023). Plaintiff seeks two remedies with respect to the section 5000D tax: injunctive and declaratory relief. *See* Compl. ¶¶ 120, 123; Proposed Order at 1–2, ECF No. 18-13. Even if such relief were available, *see infra* Part IV.A.2, neither remedy would provide Plaintiff with any redress, and Plaintiff therefore lacks standing.

Take the requested injunctive relief first. Plaintiff alleges that the excise tax is "imposed for a failure to 'agree' with the government's maximum fair price" and that this imposition is "punitive" in violation of the Excessive Fines Clause. Compl. ¶ 110; *see also id.* ¶ 63 (asserting tax "punish[es] a manufacturer that fails to 'agree' to the government's pricing scheme for a particular drug"). Plaintiff then asks the Court to "[e]njoin Defendants from forcing Novartis . . . to 'agree' to prices set by the Program" by way of the excise tax. *Id.* ¶ 123; *see also* Proposed Order at 2 ("Defendants are

permanently enjoined from enforcing against Plaintiff any obligation to enter any 'agreement' under [the IRA]"). But Defendants—HHS and CMS—do not administer the IRA's tax provisions, which are codified in the Internal Revenue Code. *See* 26 U.S.C. § 5000D. Rather, the Department of the Treasury, of which the IRS is a part, is charged with enforcing section 5000D and interpreting its provisions. *Compare id.* § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance . . . ."), *with id.* § 5000D(b)(1)(B) (referring to "the Secretary of Health and Human Services"), *and id.* § 5000D(c)(1)(A)(i) (same); *see also* 26 U.S.C. § 7701(a)(11)(B) ("When used in this title, [unless otherwise stated], [t]he term 'Secretary' means the Secretary of the Treasury or his delegate."). As Plaintiff acknowledges, *see* Pl.'s Br. at 38, under this authority, Treasury has issued a notice explaining how it interprets section 5000D. *See* IRS Notice. The notice explains that the "Treasury Department and the IRS"—not HHS or CMS—"intend" to issue "forthcoming proposed regulations" regarding the scope of taxable sales, *see id.* § 3.01, and the applicable tax percentage, *see id.* § 3.02.

Accordingly, the injunction Plaintiff requests cannot redress any tax-based injuries in this suit. Defendants are not the agencies that would assess or collect any tax and, even though Treasury and the IRS are of course federal agencies, the Court cannot enter judgment against them because they are "not parties to the suit" and they would not be "obliged to honor an incidental legal determination the suit produced." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 569 (1992) (plurality opinion); *see also id.* at 570–71 ("The short of the matter is that redress of the only injury in fact respondents complain of requires action . . . by the individual funding agencies; and any relief the District Court could have provided in this suit against the Secretary was not likely to

produce that action."). The Supreme Court recently reaffirmed that a plaintiff lacks Article III standing to secure an injunction if it fails to sue the entities allegedly responsible for its purported injuries. *See Brackeen*, 599 U.S. at 292 ("enjoining the federal parties would not remedy the alleged injury" because other entities carry out the challenged provisions). Whatever injury Plaintiff might one day suffer "at the hands" of Treasury and the IRS "is insufficient by itself to establish a case or controversy in the context of this suit, for [neither Treasury nor the IRS] is a defendant." *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41 (1976).

Plaintiff's "request for a declaratory judgment"—asking the Court to "[d]eclare that the Program's 'excise tax' violates the Excessive Fines Clause," Compl. ¶ 120—"suffers from the same flaw." *Brackeen*, 599 U.S. at 293. "[J]ust like suits for every other type of remedy, declaratory-judgment actions must satisfy Article III's case-or-controversy requirement." *California v. Texas*, 141 S. Ct. 2104, 2115 (2021). Declaratory relief "conclusively resolves 'the legal rights *of the parties*.'" *Brackeen*, 599 U.S. at 293 (quoting *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 200 (2014)); *see also Md. Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) ("[T]he question in each case is whether the facts alleged . . . show that there is a substantial controversy, *between parties having adverse legal interests* . . . to warrant the issuance of a declaratory judgment." (emphasis added)). "But again, [Treasury and IRS] are nonparties who would not be bound by the judgment." *Brackeen*, 599 U.S. at 293. Thus, Plaintiff's excise-tax challenge "would not be settled between [Plaintiff] and the officials who matter—which would leave the declaratory judgment powerless to remedy the alleged harm." *Id.* And "[w]ithout preclusive effect, a declaratory judgment is little more than

an advisory opinion." *Id.*; *see also California*, 141 S. Ct. at 2115 ("Remedies . . . operate with respect to specific parties. In the absence of any specific party, they do not simply operate on legal rules in the abstract." (cleaned up)).

The mere possibility that a court's "legal reasoning may inspire or shame others into acting differently" is immaterial; rather, courts "measure redressability by asking whether a court's judgment will remedy the plaintiff's harms." *United States v. Texas*, 143 S. Ct. 1964, 1979 (2023) (Gorsuch, J., concurring). After all, "[i]t is a federal court's judgment, not its opinion, that remedies an injury; thus it is the judgment, not the opinion, that demonstrates redressability." *Brackeen*, 599 U.S. at 294. Because Plaintiff "can hope for nothing more than an opinion" in this suit against HHS and CMS, it "cannot satisfy Article III" as to the excise-tax claim. *See id.*

2. The AIA and the tax exception to the DJA prohibit this Court from adjudicating Plaintiff's excise-tax claim

Plaintiff's excise-tax claim is independently barred by the AIA and the tax exception to the DJA. "Congress has expressly invoked sovereign immunity with respect to virtually all tax assessment challenges and demands for declaratory and injunctive relief under the [Internal Revenue Code]." *United States v. Stuler*, 396 F. App'x 798, 800 (3d Cir. 2010) (citing 26 U.S.C. § 7421(a); 28 U.S.C. § 2201). Under the AIA, "no court has jurisdiction over a suit" like this one "to preemptively challenge a tax." *RYO Mach., LLC v. Dep't of Treasury*, 696 F.3d 467, 470 (6th Cir. 2012). And, for AIA purposes, a "tax" is any exaction—like the excise tax—that Congress has "label[ed]" as such. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544, 564 (2012); *see also* 26 U.S.C. § 5000D (labeling excise tax as a "tax"). This Court is similarly prohibited from granting

the declaratory relief that Plaintiff seeks because the tax exception to the DJA bars courts from issuing declaratory judgments "with respect to Federal taxes." 28 U.S.C. § 2201(a). Because Plaintiff asks the Court to preemptively enjoin, and declare the constitutionality of, the section 5000D tax, this claim must be dismissed.

a. The AIA deprives this Court of jurisdiction over the excise-tax claim

No court may "restrain[] the assessment or collection of any tax." 26 U.S.C. § 7421(a). "The [AIA] apparently has no recorded legislative history, but its language could scarcely be more explicit—'no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court . . . .'" *Bob Jones Univ. v. Simon*, 416 U.S. 725, 736 (1974). "Because of the [AIA], taxes can ordinarily be challenged only after they are paid, by suing for a refund." *NFIB*, 567 U.S. at 543; *Flynn v. U.S. ex rel. Eggers*, 786 F.2d 586, 588 (3d Cir. 1986) (AIA requires tax challenges "be determined in a suit for refund").

The AIA's jurisdictional bar applies with equal force to constitutional challenges to a tax. The Supreme Court has made "it unmistakably clear that the constitutional nature of a taxpayer's claim . . . is of no consequence under the [AIA]." *Alexander v. Ams. United Inc.*, 416 U.S. 752, 759 (1974). "[N]otwithstanding that [Plaintiff] [has] couched [its] tax collection claim in constitutional terms," it "seek[s] to restrain the Government's collection of taxes, which is precisely what the [AIA] prohibits." *We the People Found., Inc. v. United States*, 485 F.3d 140, 143 (D.C. Cir. 2007); *see also Franklin v. United States*, No. 3:20-cv-1303, 2021 WL 4458377, at *7 (N.D. Tex. Sept. 29, 2021)

(“couching” tax challenge “in constitutional terms” insufficient to contravene AIA), *aff’d*, 49 F.4th 429 (5th Cir. 2022).

i. To determine whether the AIA applies, courts ask (1) whether the exaction at issue is a “tax,” and (2) whether the purpose of the claim is to “restrain[] the assessment or collection” of that tax. 26 U.S.C. § 7421(a). Because both are true here, the excise-tax claim is barred by the AIA.

First, the section 5000D excise tax is a “tax” for AIA purposes because Congress “label[ed]” it as such. *See NFIB*, 567 U.S. at 564. The AIA and the IRA’s excise tax are “creatures of Congress’s own creation” and, therefore, “[h]ow they relate to each other is up to Congress, and the best evidence of Congress’s intent is the statutory text.” *Id.* at 544. Accordingly, “even where [a] label was inaccurate” for constitutional purposes, the Supreme Court has “applied the [AIA]” to bar preemptive challenges “to statutorily described ‘taxes.’” *Id.* (citation omitted); *id.* at 564 (“It is up to Congress whether to apply the [AIA] to any particular statute, so it makes sense to be guided by Congress’s choice of label on that question.”). Simply put, “the [AIA’s] reach depends on statutory labels.” *In re Juntoff*, 76 F.4th 480, 485 (6th Cir. 2023); *see also Optimal Wireless LLC v. IRS*, 77 F.4th 1069, 1074 (D.C. Cir. 2023) (looking to statutory references to determine whether exaction is tax for AIA purposes); *Matter of Westmoreland Coal Co.*, 968 F.3d 526, 534 (5th Cir. 2020) (“With the AIA, form—specifically, the label Congress uses—does matter over substance.”). That is, the AIA “draws no distinction between regulatory and revenue-raising tax rules”; rather, if the exaction is labeled a tax by Congress, it is a tax for AIA purposes. *See CIC Servs., LLC v. IRS*, 593 U.S. 209, 225 (2021).

Congress labeled the excise tax a "tax." Section 5000D refers to a "tax" nearly a half dozen times. *See* 26 U.S.C. § 5000D(a) ("There is hereby imposed on the sale by the manufacturer . . . of any designated drug . . . a tax . . . ."); *id.* § 5000D(a)(1) (referring to "such tax"); *id.* § 5000D(a)(2) (same); *id.* § 5000D(c) ("Suspension of Tax"). The final reference is especially direct: "[i]n the case of a sale which was timed for the purpose *of avoiding the tax imposed by this section*, the Secretary may treat such sale as occurring during a day described in [the subsection defining periods to which the tax applies]." *Id.* § 5000D(f)(2) (emphasis added). Further, Congress codified section 5000D in Title 26—*i.e.*, the Internal Revenue Code—separate from the rest of the IRA's drug-negotiation provisions. *See* Pub. L. No. 117-169, § 11003 ("Subtitle D of the Internal Revenue Code of 1986 is amended by adding at the end the following . . . ."). For AIA purposes, the statutory text is clear: section 5000D imposes a "tax."

Second, the purpose of Plaintiff's excise-tax claim is to "restrain[]" the "assessment or collection" of the section 5000D tax. 26 U.S.C. § 7421(a). In considering a claim's purpose, courts look to "the claims brought and injuries alleged" as well as "the relief the suit requests." *CIC Servs.*, 593 U.S. at 217. The excise-tax claim squarely targets the tax. *See, e.g.*, Compl. ¶ 112 (the "excise tax is . . . unconstitutional under the Excessive Fines Clause of the Eighth Amendment"); *see also id.* ¶¶ 63–71, 108–11. *Cf. CIC Servs.*, 593 U.S. at 219 ("The complaint contests the legality of [an IRS notice], not of the statutory tax penalty that serves as one way to enforce it. CIC alleges that the Notice is procedurally and substantively flawed; it brings no legal claim against the separate statutory tax."). And the relief requested here to "[e]njoin Defendants from forcing Novartis . . . to 'agree' to prices set by the Program"—which Plaintiff says

is accomplished by "impos[ing]" a "clearly punitive" "excise tax"—asks the Court to restrain the assessment or collection of that tax. Compl. ¶¶ 110, 123. "These allegations leave little doubt that a primary purpose of" the tax claim "is to prevent the [IRS] from assessing and collecting" the excise tax. *Bob Jones*, 416 U.S. at 738.

ii. "Exceptions to [the AIA's] express prohibition have been allowed only in limited areas and for extraordinary circumstances." *Thornton v. United States*, 493 F.2d 164, 166 (3d Cir. 1974). Neither of the two judicially created exceptions—the *Williams Packing* and the *South Carolina* exceptions—applies here. *See South Carolina v. Regan*, 465 U.S. 367 (1984); *Enochs v. Williams Packing & Navig. Co.*, 370 U.S. 1 (1962).

A taxpayer's "burden under *Williams Packing* is very substantial." *Flynn*, 786 F.2d at 591. This "stringent" exception requires "proof of the presence of two factors" to avoid "the literal terms of" the AIA: "first, irreparable injury, the essential prerequisite for injunctive relief in any case; and second, certainty of success on the merits." *Bob Jones*, 416 U.S. at 737 (discussing *Williams Packing*, 370 U.S. at 6). "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." *Am. United*, 416 U.S. at 758. Neither one is met here.

First, because a refund suit is an adequate remedy, Plaintiff cannot establish that it will suffer irreparable harm absent preemptive injunctive relief. *See Gaetano v. United States*, 942 F.3d 727, 734 (6th Cir. 2019). "This is not a case in which an aggrieved [taxpayer] has no access at all to judicial review." *Bob Jones*, 416 U.S. at 746. A manufacturer that wishes to challenge the excise tax could pay it, seek a refund from the IRS, then sue for a refund in district court or the Court of Federal Claims. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491; *see also Sutherland v. Egger*, 605 F. Supp. 28,

31 (W.D. Pa. 1984) ("plaintiffs have an adequate remedy at law, a refund suit"). That is particularly true given that the excise tax is imposed on each "sale" of a designated drug, 26 U.S.C. § 5000D(a), and is thus a "divisible tax," meaning "one that represents the aggregate of taxes due on multiple transactions (*e.g.*, sales of items subject to excise taxes)," *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). A taxpayer challenging a divisible tax need only pay "the excise tax on a single transaction [to] satisfy" the rule that it must fully pay the tax before seeking a refund. *Id.*; *see also Flora v. United States*, 362 U.S. 145, 171–75 nn.37, 38 (1960). And, while a refund suit is pending, the IRS typically does not collect the balance of any divisible tax that would otherwise be due, except when unusual circumstances warrant. IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6) ("When a refund suit is pending on a divisible assessment, the Service will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy.").

Second, in any event, even a showing of irreparable harm would be insufficient to set aside the AIA. *See Williams Packing*, 370 U.S. at 6. Plaintiff would also have to show that, "under the most liberal view of the law and the facts," "it is clear that under no circumstances could the Government ultimately prevail" on its defense of the merits. *Id.* at 7; *see also Flynn*, 786 F.2d at 591. A plaintiff can satisfy this second prong only if it establishes "certainty of success on the merits." *Bob Jones*, 416 U.S. at 737. This high bar is rarely met. *See, e.g.*, *Williams Packing*, 370 U.S. at 8 (government's defense of tax "was not without foundation"); *Beale v. IRS*, 256 F. App'x 550, 551 (3d Cir. 2007) (not "clear that under no circumstances could the Government ultimately prevail"); *Cohen v. Gross*, 316 F.2d 521, 523 (3d Cir. 1963) (tax not "unquestionably illegal"). And, as set

forth below, *see infra* at 48–60, it is plainly not met here either, particularly given that no court, to Defendants' knowledge, has ever held that a tax—let alone one, like the excise tax, lacking any connection to criminal conduct or a criminal proceeding—was a fine for Excessive Fines Clause purposes.

The *South Carolina* exception similarly offers no safe harbor. That exception is a "very narrow" one that applies only when "Congress has not 'provided an alternative avenue for an aggrieved party to litigate its claims,'" necessitating the party harmed by the tax to find a third party to assert the legal issues. *RYO Mach.*, 696 F.3d at 472 (quoting *South Carolina*, 465 U.S. at 381). This case is a far cry from "the unique factual pattern" in *South Carolina*, where the state could not bring a refund suit itself and had to rely on third-party bondholders to challenge a change in the tax code that stripped certain state-issued bonds of their tax-exempt status. *Id.* (quoting *Am. Soc. of Ass'n Execs. v. Bentsen*, 848 F. Supp. 245, 250 (D.D.C. 1994)).

b. The DJA tax exception bars declaratory relief regarding the excise tax

Plaintiff's attempt to obtain declaratory relief also fails. "[T]he federal tax exception to the [DJA] is at least as broad as the [AIA]." *Bob Jones*, 416 U.S. at 733 n.7; *see also Ams. United*, 416 U.S. at 759 n.10 (same). Accordingly, courts lack jurisdiction to issue declaratory relief regarding challenged tax provisions. *See, e.g.*, *Larson v. United States*, 888 F.3d 578, 589 (2d Cir. 2018) (Eighth Amendment claim barred by DJA); *Rivero v. Fid. Invs., Inc.*, 1 F.4th 340, 344 (5th Cir. 2021) ("the DJA's federal-tax exception imposes a jurisdictional condition that was not met"). Thus, declaratory relief is barred for the same reasons that the AIA bars enjoining assessment or collection of the tax.

* * *

In short, multiple independent jurisdictional bars preclude this Court from evaluating the merits of Plaintiff's Eighth Amendment claim. That claim should therefore be dismissed.

B. Even if the Court had jurisdiction over Plaintiff's Eighth Amendment claim, that claim would fail on the merits

Even if the Court were to reach the merits of the excise-tax claim, that claim would fail because the tax does not violate the Excessive Fines Clause. The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII. "Taken together, these Clauses place 'parallel limitations' on 'the power of those entrusted with the criminal-law function of government.'" *Timbs v. Indiana*, 139 S. Ct. 682, 687 (2019) (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 263 (1989)). "The purpose of the Eighth Amendment"—both the Excessive Fines Clause and the Cruel and Unusual Punishments Clause—"was to limit the government's power to punish." *Austin v. United States*, 509 U.S. 602, 609 (1993). The threshold question in any Excessive Fines Clause case then is whether the challenged exaction constitutes "punishment for an offense"—*i.e.*, whether it is a "fine" covered by the Eighth Amendment. *United States v. Bajakajian*, 524 U.S. 321, 328 (1998). Only if the exaction is deemed punishment does a court consider whether the fine is unconstitutionally excessive.

The excise tax does not violate the Excessive Fines Clause because it is neither a "fine" nor "excessive." The excise tax is not a "fine" covered by the Eighth

Amendment because it is not "punishment for some offense." *Bajakajian*, 524 U.S. at 327. The excise tax has no connection to a criminal offense or criminal proceedings—unlike the exactions at issue in the Excessive Fines Clause precedents that Plaintiff cites. The excise tax also lacks the "unusual features" of the drug taxes in *Kurth Ranch* and *Dye* that led the Supreme Court and the Seventh Circuit, respectively, to conclude that those taxes constituted punishment for purposes of the Double Jeopardy Clause. Even if the excise tax were a fine, the proportionality test—which itself looks to the "gravity of the offense," a factor that has no bearing here given the lack of any offense—demonstrates that the excise tax is not grossly disproportionate to the harm to the fisc and is within the range of other constitutional exactions.

1. "[A]t the time of the Framing, the Founders understood "'fine" . . . to mean a payment to a sovereign as punishment for some offense."' *United States v. Cheeseman*, 600 F.3d 270, 282 (3d Cir. 2010) (quoting *Bajakajian*, 524 U.S. at 327). "Then, as now," fines were typically imposed as punishments in criminal prosecutions. *Browning-Ferris Indus.*, 492 U.S. at 265. While the Supreme Court has found certain civil penalties and forfeitures to constitute "punishment" within the scope of the Excessive Fines Clause, it has done so only in cases where the penalty or forfeiture either constituted a post-conviction sanction, *see Bajakajian*, 524 U.S. at 325 (person convicted of willfully violating reporting requirement shall forfeit property "involved in such offense"), or was assessed against property used in the commission of a crime for which the owner had been convicted, *see Austin*, 509 U.S. at 622 (property used to facilitate drug crimes subject to civil forfeiture). The Court has never characterized an exaction with no

connection to either criminal activity or a criminal proceeding as "punishment for some offense," let alone punishment that violates the Excessive Fines Clause.

Plaintiff does not cite any case that does so—from the Third Circuit or elsewhere. *See* Pl.'s Br. at 35–40. Instead, the two excessive fines cases Plaintiff cites in which the forfeiture or penalty was held to be "punishment"—*Austin* and *Bajakajian*—involved criminal conduct or criminal proceedings. Neither case involves taxes or otherwise bears any resemblance to this case.

Take *Austin* first. After Austin pleaded guilty to cocaine possession, the government sought forfeiture of his mobile home and auto shop pursuant to provisions that made property used in furtherance of certain crimes subject to civil forfeiture. *Austin*, 509 U.S. at 604–05 (citing 21 U.S.C. § 881(a)(4), (7)). Both history and modern practice demonstrated that these provisions constituted punishment. The Court concluded that, "at the time the Eighth Amendment was ratified," forfeiture was understood "as imposing punishment." *Id.* at 611–18. And three features of these provisions demonstrated that they remained "punishment today": (1) the "inclusion of innocent-owner defenses," which reveals a "congressional intent to punish only those involved in drug trafficking"; (2) "Congress [having] chosen to tie forfeiture directly to the commission of drug offenses"; and (3) a legislative history that indicates "Congress recognized 'that the traditional criminal sanctions of fine and imprisonment are inadequate to deter or punish the enormously profitable trade in dangerous drugs.'" *Id.* at 619–20 (citation omitted). Taken together, these forfeiture provisions constituted "punishment for some offense" subject to the Excessive Fines Clause. *Id.* at 622.

Bajakajian, meanwhile, is a *criminal* forfeiture case. After Bajakajian tried to leave the country without reporting over $350,000 in cash, he was charged with three counts. 524 U.S. at 325. The third sought forfeiture of the unreported funds pursuant to 18 U.S.C. § 982(a)(1), which provides that, "in imposing sentence on a person convicted of [failure-to-report crime]," the court "shall order that the person forfeit . . . any property . . . involved in such offense." *Id.* The Court held that this forfeiture was "punishment" under the Excessive Fines Clause. *Id.* at 328–34. Again, the Court looked to history, concluding that such forfeitures "have historically been treated as punitive, being part of the punishment imposed for felonies and treason in the Middle Ages and at common law." *Id.* at 332. The modern version remained "punishment": the forfeiture is "imposed at the culmination of a criminal proceeding and requires conviction of an underlying felony, and it cannot be imposed upon an innocent owner of unreported currency, but only upon a person who has himself been convicted of a [criminal] reporting violation." *Id.* at 328.

None of the features of the civil forfeiture in *Austin* or the criminal forfeiture in *Bajakajian* is present here. *See United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022) ("[U]nlike [the] forfeitures held to constitute 'punishment' in both *Austin* and *Bajakajian*, this civil penalty"—"imposed following an administrative tax audit"—"is not tied to any criminal sanction."), *cert. denied*, 143 S. Ct. 552 (2023). Unlike civil or criminal forfeiture, "taxes historically have not been viewed as punishment." *United States v. Beaty*, 147 F.3d 522, 525 (6th Cir. 1998). The other three *Austin* factors are similarly absent. First, section 5000D does not contain an innocent-taxpayer exception and imposition of the tax does not depend on any particular level of culpability. *See generally*

26 U.S.C. § 5000D. Second, the excise tax is not tied to the commission of any crime; rather, tax liability is triggered by the lawful choices of the taxpayer in connection with the Negotiation Program. *See id.* § 5000D(a), (b), (e)(1). Third, Congress did not indicate that the tax is meant to supplement "traditional criminal sanctions of fine and imprisonment" to adequately "deter or punish" illegal activity. *See Austin*, 509 U.S. at 620. And, unlike the criminal forfeiture in *Bajakajian*, the excise tax is not "imposed at the culmination of a criminal proceeding," does not "require[] [a] conviction of an underlying felony," and does not distinguish in its rate or scope between different levels of culpability. *See Bajakajian*, 524 U.S. at 328.

2. Having identified no case in which an exaction untethered from criminal conduct or criminal proceedings was deemed "punishment for some offense" under the Excessive Fines Clause, Plaintiff turns to two Double Jeopardy Clause cases. *See* Pl.'s Br. at 36–37 (citing *Dep't of Revenue of Montana v. Kurth Ranch*, 511 U.S. 767 (1994); *Dye v. Frank*, 355 F.3d 1102 (7th Cir. 2004)). Those are the *only* cases Plaintiff identifies in which a tax was held to be punishment; it does not cite *any* case (and Defendants are not aware of one) in which a tax was deemed to be "punishment for some offense" (*i.e.*, a "fine") under the Excessive Fines Clause. And both cases—involving drug taxes related to criminal offenses—reinforce why the tax here is *not* punishment.

As a preliminary matter, the analytical framework used by the Supreme Court in *Kurth Ranch* undermines a core premise of Plaintiff's argument: that the excise tax is a "fine" if it "serv[es] in part to punish." Pl.'s Br. at 36 (quoting *Austin*, 509 U.S. at 610). The Court first adopted that test in *United States v. Halper*, 490 U.S. 435 (1989), a case involving a $130,000 civil penalty on the heels of a 65-count criminal conviction that

also resulted in a two-year prison sentence and a $5,000 fine. *Id.* at 437–38. Because the post-conviction civil fine could not "fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes," the Court held it was "punishment" for Double Jeopardy purposes. *Id.* at 448.[10]

The Supreme Court has never applied this deterrent-in-part test in the tax context, and, in *Kurth Ranch*, the Court rejected its application to a state drug tax. 511 U.S. at 776. As the Third Circuit has recognized, *Kurth Ranch* "announc[ed] that the 'no deterrent purpose' rule of *Halper* and *Austin* does not apply in all situations." *Artway v. Att'y Gen. of State of N.J.*, 81 F.3d 1235, 1258 (3d Cir. 1996); *see also United States v. $184,505.01 in U.S. Currency*, 72 F.3d 1160, 1166 (3d Cir. 1995) ("[T]he Court found the *Halper* method of determining whether a civil sanction is punitive to be inapplicable to tax statutes."). In *Kurth Ranch*, the Court concluded that the *Halper* test was inapplicable to a Double Jeopardy Clause challenge to a Montana tax on illegal drug possession because, while *Halper* held that certain civil *penalties* could constitute punishment, "*Halper* did not . . . consider whether a *tax* may similarly be characterized as punitive." 511 U.S. at 776, 778 (emphasis added). Because "tax statutes serve a purpose quite different from civil penalties," "*Halper*'s method of determining whether the exaction was remedial or punitive 'simply does not work in the case of a tax statute.' Subjecting Montana's drug tax to *Halper*'s test for civil penalties is therefore inappropriate." *Id.* at 784 (citation omitted). Accordingly, "neither a high rate of taxation nor an obvious

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[10] The Court later abrogated *Halper* in *Hudson v. United States*, 522 U.S. 93, 102 (1997) (noting that "all civil penalties have some deterrent effect" and rejecting "*Halper*'s test for determining whether a particular sanction is 'punitive'" under the Double Jeopardy Clause).

deterrent purpose automatically marks [a] tax as a form of punishment." *Id.* at 780. "Whereas fines, penalties, and forfeitures are readily characterized as sanctions," absent "[o]ther unusual features," "an exaction labeled as a tax" is not deemed punishment, even if it is accompanied by a "deterrent purpose." *Id.* at 779–81; *id.* at 780–81 ("[M]any taxes that are presumed valid, such as taxes on cigarettes and alcohol, are also both high and motivated to some extent by an interest in deterrence . . . ."); *contra* Pl.'s Br. at 36–37.

The facts of *Kurth Ranch* are equally unhelpful to Plaintiff. The marijuana tax there was deemed "punishment" only because of a host of "unusual features" and "anomalies" absent here. Concluding that the tax's high rate and admittedly deterrent purpose did "not necessarily render the tax punitive," the Court identified three additional, "unusual features" that led the Court to label the "exceptional" Montana tax as punishment. *Id.* at 781, 783. First, Montana's "so-called tax"[11] was "conditioned on the commission of a crime." *Id.* at 781. Second, it was "exacted only after the taxpayer has been arrested for the precise conduct that gives rise to the tax obligation in the first place" such that "[p]ersons who have been arrested for possessing marijuana constitute[d] the entire class of taxpayers subject to the Montana tax." *Id.* at 781–82. Third, the tax was "levied . . . on previously confiscated goods" that the "taxpayer neither own[ed] nor possess[ed] when the tax [was] imposed." *Id.* at 783. Because of

[11] Plaintiff similarly refers to the section 5000D tax as a "so-called 'tax.'" Pl.'s Br. at 36. That characterization, as the Court's own description of the Montana drug tax shows, does not alter the punishment analysis. What mattered for purposes of the Court's decision in *Kurth Ranch* was that the Montana tax was "labeled as a tax." 511 U.S. at 780. Given that label, the Court refused, unlike in *Halper* and *Austin*, to hold that the tax constituted punishment on the sole basis that the tax partly had a deterrent purpose.

this "concoction of anomalies," the Court held that the tax was "too far-removed in crucial respects from a standard tax assessment to escape characterization as punishment." *Id.*

None of the "unusual features" that made the Montana tax "exceptional" is present here: the excise tax is not conditioned on the commission of a crime, it is not exacted after an arrest, and it is not levied on previously confiscated goods. *See id.* at 781–83. Indeed, the tax does not follow any determination that the taxpayer has engaged in any unlawful activity. *See generally* 26 U.S.C. § 5000D. Further, unlike the tax assessment in *Kurth Ranch*, which required the taxpayer to pay a *multiple* of gross revenue (approximately four times), 511 U.S. at 780 n.17, a manufacturer's excise-tax obligations may be satisfied by paying a *fraction* of gross revenue because the tax, when not separately invoiced, ranges from 65% to 95% of the amount charged for a designated drug, IRS Notice § 3.02; *see also* 26 U.S.C. § 5000D(d).[12]

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[12] Plaintiff maintains that the tax reaches "*nineteen times* the manufacturer's nationwide revenues." Pl.'s Br. at 37. But the IRS has made clear, in a notice that "taxpayers may rely on" now, IRS Notice § 4; *contra* Pl.'s Br. at 8 n.2, that—assuming a manufacturer does not separately invoice the tax and assuming 271 days have passed—a covered taxpayer would owe a $95 tax out of $100 charged for a drug by a manufacturer—that is 95%, not 1900%. *See* IRS Notice § 3.02. Further, that notice explains that the tax applies only to sales "*under the terms of Medicare*"—*i.e.*, only those drugs dispensed, furnished, or administered to Medicare beneficiaries. *Id.* § 3.01 (emphasis added). Plaintiff appears to dispute IRS's interpretation of section 5000D, *see* Pl.'s Br. at 38–40, but Plaintiff does not bring a standalone claim as to the notice. That is unsurprising, given that the IRS's interpretation—at least in comparison to the one advanced by Plaintiff—operates to Plaintiff's benefit, and Plaintiff would therefore lack standing to challenge it. In any event, because Plaintiff brings a facial challenge—before any tax has been assessed or collected, in violation of the AIA—it must establish that the tax is unconstitutional in all applications. *City of Los Angeles v. Patel*, 576 U.S. 409, 418 (2015).

Further, unlike the tax in *Kurth Ranch*, the excise tax serves a remedial purpose in compensating the public fisc for losses incurred from a manufacturer failing to agree to a maximum fair price and continuing to sell its drugs to Medicare beneficiaries, potentially at much higher prices. Indeed, courts regularly recognize that tax *penalties*—which would appear to have a greater deterrent purpose than taxes themselves—have a remedial purpose. *See Helvering v. Mitchell*, 303 U.S. 391, 401 (1938) (describing "[t]he remedial character of sanctions imposing additions to a tax"); *Dewees v. United States*, 272 F. Supp. 3d 96, 100–01 (D.D.C. 2017) ("courts have erected 'an insurmountable wall of tax cases' to support [the] proposition" that "tax penalties are remedial"), *aff'd*, 767 F. App'x 4 (D.C. Cir. 2019).[13]

The Seventh Circuit's decision in *Dye* is similarly inapposite. Dye appealed the denial of a habeas petition he filed after being criminally charged for cocaine possession subsequent to a civil action to collect unpaid controlled substances taxes on the same

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Therefore, to the extent the parties have a dispute about the applicable rate of tax that would apply, Plaintiff is entitled to relief only if the excise tax is unconstitutional applying IRS's interpretation of its scope and rate.

[13] Plaintiff asserts, without citation, that "the government itself does not anticipate deriving any revenue from" the excise tax. Pl.'s Br. at 3. Plaintiff appears to be referring here to Congressional Budget Office (CBO) projections. *See* Compl. ¶ 5 (citing CBO predictions). To the extent that Plaintiff is contending that a CBO prediction can determine whether a tax has a remedial purpose, Plaintiff is wrong. "[A] CBO cost estimate is not persuasive evidence of congressional intent." *Laumann v. NHL*, 56 F. Supp. 3d 280, 296 (S.D.N.Y. 2014); *see also Sharp v. United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009) ("the CBO is not Congress, and its reading of the statute is not tantamount to congressional intent"). Regardless, Plaintiff's argument confuses purposes and effects. The excise tax can and does have a remedial purpose even if, by Plaintiff's telling, a manufacturer would not engage in the conduct that would cause the harm the excise tax is designed to remedy. *Cf. United States v. Sanchez*, 340 U.S. 42, 44 (1950) (tax is valid "even [if it] definitely deters the activity taxed").

cocaine. 355 F.3d at 1103. Applying a seven-factor test, the court held that the Wisconsin drug tax was the "rare tax statute" that "is so punitive in either purpose or effect that it is subject to double jeopardy analysis at all." *Id.* at 1108. The court's holding rested on key facts missing here: "the tax is only applied to behavior that is already a crime," was "created in order to deter criminal conduct," and the amount of the tax was "approximately five times the market value of the drugs" ($400 tax assessment and penalty on a gram of cocaine that could be sold for "approximately $80"). *Id.* at 1104–05. Based on these facts, and the similarities with the *Kurth Ranch* tax, the court described the drug tax as "criminal punishment masquerading as a civil tax" such that further criminal proceedings risked punishing Dye twice "for his misconduct." *Id.* at 1108. Again, none of these features are present here.

3. The test used to determine whether a "fine" is "excessive" under the Excessive Fines Clause only reinforces the conclusion that the excise tax is not "punishment." A fine is not excessive if the "amount of the [fine] bear[s] *some* relationship to the gravity of the offense that it is designed to punish," an inquiry that requires a court to "compare the amount of the [fine] to the gravity of the defendant's offense." *Bajakajian*, 524 U.S. at 334, 336–37 (emphasis added). That question has no bearing here given the lack of any "offense" or any "design[] to punish." *Id.* at 334.

Plaintiff nonetheless argues that "it goes without saying" that the excise tax is "grossly disproportionate" because the excise tax punishes "totally innocent conduct." Pl.'s Br. at 38; *see also* Compl. ¶ 70 (alleging tax does not punish "misconduct at all, let alone an 'offense'"). That is precisely the point: because the tax is not triggered by the commission of *any* offense—reprehensible or otherwise—it is not "punishment for

some offense" and therefore is not a "fine" under the Excessive Fines Clause. Embracing Plaintiff's argument would lead to absurd results: *most* taxes would be unconstitutionally disproportionate because they are assessed following innocuous conduct like working or shopping. That would stretch the Eighth Amendment, which merely "limit[s] the government's power to punish," beyond recognition. *Austin*, 509 U.S. at 609.

4. If the Court were to reach the excessiveness inquiry, the excise tax would not be a "grossly disproportionate" fine. First, "strict proportionality" is not required; a fine is constitutional unless it is grossly disproportional to the offense. *Bajakajian*, 524 U.S. at 336 (adopting "standard of gross disproportionality articulated in" "Cruel and Unusual Punishments Clause precedents"). Second, that inquiry requires "substantial deference" to Congress. *Solem v. Helm*, 463 U.S. 277, 290 (1983); *Bajakajian*, 524 U.S. at 336 ("judgments about the appropriate punishment for an offense belong in the first instance to the legislature"). Because "Congress is a representative body, its pronouncements regarding the appropriate range of fines for a crime represent the collective opinion of the American people as to what is and is not excessive." *United States v. 817 N.E. 29th Dr.*, 175 F.3d 1304, 1309 (11th Cir. 1999). "Given that excessiveness is a highly subjective judgment, the courts should be hesitant to substitute their opinion for that of the people." *Id.* There is thus a "strong presumption" that a fine "within the range of fines prescribed by Congress . . . is constitutional." *Id.* That is especially so in the tax context, where "the appropriate level or rate of taxation is essentially a matter for legislative, and not judicial, resolution." *Commonwealth Edison Co. v. Montana*, 453 U.S. 609, 627 (1981).

Plaintiff fails to overcome the "strong presumption" of constitutionality here, as the *Bajakajian* factors make clear. First, unlike in *Bajakajian*, where the defendant who failed to report the cash in his possession did "not fit into the class of persons for whom the statute was principally designed" because he was not a "money launderer, a drug trafficker, or a tax evader," 524 U.S. at 338, any "manufacturer" "of any designated drug" against whom the excise tax is assessed is an entity for which that statute was designed—a point Plaintiff does not contest. 26 U.S.C. § 5000D(a). Second, while the "[f]ailure to report" currency "caused no loss to the public fisc" in *Bajakajian*, 524 U.S. at 339 (government "deprived only of . . . information"), here the fisc will likely incur significant losses, and seniors will likely face substantially higher costs, if a manufacturer that chooses to continue participating in Medicare declines to agree to a maximum fair price and sells that drug to Medicare at a higher price than the statutory ceiling. Third, unlike in *Bajakajian*, where there was "no inherent proportionality" in requiring forfeiture of the full amount of undisclosed cash, *see id.*, the excise tax is proportional to the harm to the fisc: where a manufacturer of a designated drug has refused to fully participate in the Negotiation Program, the more it sells its drug to Medicare (presumably at a price higher than that which the manufacturer could have agreed to as a "maximum fair price"), the greater the loss to the public and the higher the tax liability. *See* 26 U.S.C.§ 5000D(b); IRS Notice at 3. Indeed, because the tax attaches only to sales of the drug that are reimbursed by Medicare, the tax necessarily recoups only a portion of the outlays that the Medicare program or Medicare beneficiaries have paid for the drug. And, where the tax is not separately invoiced, the ratio of the tax to the amount charged by the manufacturer—between 65% and 95%—is within the range of

constitutionally permissible exactions. *See, e.g.*, *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996) (81% civil fraud penalty).[14]

Accordingly, even if Plaintiff had sued the proper defendant and even if the AIA and DJA did not preclude jurisdiction, Plaintiff's Eighth Amendment claim would fail on the merits because the excise tax is neither a fine nor a grossly disproportionate one.

CONCLUSION

For these reasons, Plaintiff's pre-enforcement challenge to the excise tax should be dismissed for lack of subject-matter jurisdiction, and the Court should deny Plaintiff's motion for summary judgment and grant Defendants' cross-motion on all other claims.

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[14] Selected drugs, by definition, have been on the market without competition for a minimum of seven years. 42 U.S.C. § 1320f-1(e). Outside experts project that each of the manufacturers of the selected drugs have recouped their fixed-cost investments in those drugs during this time period, long in advance of the drug's selection for negotiation. *See* Richard G. Frank & Caitlin Rowley, *Medicare Negotiations Won't Keep Big Pharma from Making a Fortune*, Bloomberg Law (Sept. 5, 2023), https://www.bloomberg.com/opinion/articles/2023-09-05/medicare-negotiations-won-t-keep-big-pharma-from-making-a-fortune; *see also* Kiu Tay-Teo et al., *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, 2019 JAMA Network Open 186875 (2019). And, once a manufacturer has recouped its fixed costs, its marginal cost of producing small-molecule drugs is generally "just pennies per pill." CBO, *Prescription Drugs: Spending, Uses, and Prices* 20 (2022), https://perma.cc/27R2-3SN4. Some manufacturers accordingly may find it to be in their business interest to continue to make Medicare-reimbursable sales of their selected drugs and to pay a portion of that Medicare reimbursement back in the form of the excise tax. *Contra* Pl.'s Br. at 37 (Novartis "could not possibly pay" "ruinous" tax).

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